

REMARKS/ARGUMENTS

Applicant requests that the amendment of March 19, 2004 not be entered. The request is being made because claim 1 has been amended differently to that presented in the previous amendment of March 19, 2004. Moreover, previously amended claim 6 has been reverted back to its original wording.

There remain 19 claims pending.

Claims 2, 4 and 17 to 19 of record have been cancelled and new claims 20 to 24 have been added which are directed to various aspects of the instant invention. Support for these claims may be found throughout the specification as originally filed.

Claims 1, 3 and 8 have been amended for greater clarity and to better define the scope of protection sought by the Applicant. In particular, claim 1 has been amended to recite a method for transforming a *dicot plant*. By virtue of the cancellation of claim 2, the dependency of claim 3 has been changed from claim 2 to claim 1. Claim 8 now recites "plasmid vector" for consistency with terminology used in the preceding claims. Support for these changes may be found throughout the specification as originally filed.

Rejection under 35 USC §112, 1st paragraph

Claims 17 to 19 of record stand rejected on the grounds that plants and seeds produced by the method of the present invention have not been adequately described in the specification.

Claims 17 to 19 have been cancelled which renders the rejection thereto moot.

Rejection under 35 USC §102(b)

Claims 1 to 2, 4, 6, 9 to 11, 14 and 16 of record remain rejected as anticipated by Songstad *et al.* and claims 1 to 2, 5 to 6 and 9 to 16 remain rejected as anticipated by Burchi *et al.* In the previous Office Action of March 30, 2000, the Examiner states that Songstad *et al.* teach transformation of intact barley embryos and orchid zygotic embryos using electrophoresis and a medium containing DNA. Using a similar DNA delivery technique, Burchi *et al.* teach transformation of intact meristems of germinating seeds, embryos, bulblets, axillary shoots and protocorms.

Applicant respectfully disagrees.

MPEP §2131 provides that:

"A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described in a single prior art reference."
Verdegaal Bros. V. Union Oil Co. of California, 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987). "The **identical invention** must be shown in as

complete detail as contained in the ... claim." [Emphasis added.] *Richardson v. Suzuki Motor Co.*, 868 F.2d 1226, 1236, 9 USPQ2d 1913, 1920 (Fed. Cir. 1989). The elements must be arranged as required by the claim.

In view of the foregoing, it is asserted that neither Songstad *et al.* nor Burchi *et al.* set forth each and every element as defined in claim 1, namely a method of transforming a *dicot plant* by electrophoresis using a low amperage current. A definition of a "plant" may be found in the description at page 5, line 15, where the term is defined as including "both mature plants as well as seedlings". A seedling is generally between 5 and 10 days old and has developing leaves and therefore, is not considered to be an embryo, seed or the like. The type of plant tissue selected for transformation (e.g. embryo, seed or *plant*) will have a correlation to the electrical resistance of the plant tissue (e.g. distance between the cathode and anode) which in turn will affect DNA migration and ultimate survival of the transformed plant tissue.

Moreover, in *Dewey & Almy Chem. Co. v. Mimex Co.*, 124 F.2d 986, 52 U.S.P.Q. 138 (2d Cir. 1942), the court explained the status of anticipation by saying:

No doctrine of the patent law is better established than that a prior patent or other publication to be an anticipation must bear within its four corners adequate directions for the practice of the patent invalidated. If the earlier disclosure offers no more than a starting point for further experiments, *if its teaching will sometimes succeed and sometimes fail*, if it does not inform the art without more how to practice the new invention, it has not correspondingly enriched the store of common knowledge, and it is not an anticipation. [Emphasis added.]

Burchi *et al.* state that the distance of the meristems from the base of the stem affected the survival of the axillary shoots, closer being better, and report that "[i]n chrysanthemum all of the *apical* shoot tips died a few days after treatment, in carnation and lisianthus only 25% survived, while about 50% of the treated *axillary* shoots in all species survived". [Emphasis added.] Songstad *et al.* report that their treatment of zygote embryos resulted in about 50% survival, further stating that two major factors affect survival of the embryos, namely strength and duration of the current, along with other experimental (e.g. chemical) factors. Accordingly, neither reference constitutes a proper anticipation of the claimed invention because the results are not controllable or reliable (e.g. sometimes succeed and sometimes fail).

On this basis, reconsideration and withdrawal of the rejection to these claims are respectfully requested.

Rejection under 35 USC §103(a)

Claims 1 to 16 of record remain rejected as obvious over Burchi *et al.* in view of Ahokas. Again, referring to the previous Office Action of March 30, 2000, the Examiner states the following:

"It would have been *prima facie* obvious to a person of ordinary skill in the art at the time the invention was made to utilize the method of transformation taught by Burchi *et al.* to transform monocots such as barley as taught by Ahokas. It would have been obvious to transform soybean given the agronomic advantages of transformed soybean and given that several different species of dicots have been successfully transformed. ... Any agronomically interesting gene such as barley oxalic acid oxidase which could have been inserted into a vector could be used to transform any plant type as described above. It would have been the optimization of process parameters to use linearized plasmid DNA."

Applicant respectfully disagrees.

In order to establish a *prima facie* case of obviousness, a rejection must satisfy the following three criteria:

1. There must be some suggestion, teaching or motivation to modify the reference or combine the references on which the rejection is based;
2. There must have been a reasonable expectation of success by the hypothetical person of ordinary skill in the art, at the time the invention was made, that the modification or combination would work to produce beneficial results; and
3. The prior art references(s) must teach or suggest all of the elements and limitations recited in the claims.

Applicant asserts that the first criteria is not met since neither of the prior art references suggest any desirability to combine the elements recited in claim 1, as amended, for transforming a *dicot plant* using electrophoresis. In order for the combination to be made, all the elements as claimed must be present in the prior art references. The combination of the references does not teach every element of the claimed invention, i.e. a method of transforming a *dicot plant* by electrophoresis using a low amperage current. Moreover, the Ahokas reference is immaterial since it teaches transformation of a "monocot" plant using electrophoresis.

In order for the second criteria to be met, a person of skill in the art should be able to arrive at a claimed invention through a minimum of experimentation.

Ahokas teaches a method for electrophoretic transfection of monocot plants, namely germinating seeds of barley and seeds of various other types with a suitable embryo. The experimental conditions used by Ahokas include, among other things, a constant current of 0.1 mA and a running time of 60 minutes.

Burchi *et al.* teach a DNA transfer method into the intact meristem of germinating seeds, embryos, bulblets, axillary shoots and protocorms using electrophoresis and state the following at page 165, 1st paragraph:

"The distance of the meristems from the base of the stem also affected their survival; in fact, most of the survived axillary shoots were situated close to the base of the stem. This can be explained by the *increased voltage applied to maintain the current at increasing distances between anode and cathode.*" [Emphasis added.]

Compared to seed, embryos and the like, it would be expected that due to the greater distance between the apical meristem of a *plant* to the positive electrode, the electrical resistance would be comparatively higher. Since a higher electrical resistance presumably requires a higher amount of voltage and/or running time to achieve adequate DNA migration, it is highly conceivable that transformation of plants compared to seed or embryos is less likely to succeed. Consistent with this assumption, Songstad *et al.* provide the following:

"The resistance attributed to plant tissue can also affect the rate of DNA migration. Under constant voltage (V), an increase in resistance (R) will decrease the current (I) and reduce DNA migration. ... *Part of the resistance of plant tissue is due to the distance between the cathode and anode. By placing the two electrodes as close to each other as possible, a lower resistance will be obtained.*

Optimal DNA migration must be balanced against survival [of plant tissue]. Two major factors that affect survival of electrophoresed explants are strength and duration of current." [Emphasis added.] (at page 9, last paragraph)

Moreover, while Ahokas used standard electrophoresis buffers such as 89 mM Tris-phosphate with EDTA, Burchi *et al.* were confined to certain types and concentrations of electrophoresis buffers since this significantly effected the amount of voltage used. At page 165, 2nd paragraph, it states that "this can be a problem in tissues with high electrical resistance or with meristems situated too far from the positive electrode." [Emphasis added.]

Based on the combined teachings of Burchi *et al.* and Ahokas, it is therefore asserted that a skilled artisan would have absolutely no reasonable expectation of success that a *plant* could be transformed with DNA by applying a low amperage current using standard buffers as described in the instant application. Moreover, there is no suggestion in the teachings of either reference, or predictability in the art, that would provide direction for a skilled artisan to follow in order to arrive at the claimed invention with any reasonable expectation of success.

In addressing the third criteria, it is asserted that neither Burchi *et al.* nor Ahokas teach or suggest all of the elements and limitations recited in the claims as discussed above.

Reconsideration and withdrawal of the rejection are respectfully requested.

The Examiner is respectfully urged to call the undersigned at (613) 232-2486 to discuss the claims in an effort to reach a mutual agreement with respect to claim limitations in the present application which will be effective to define the patentable subject matter if the present claims are not deemed to be adequate for this purpose.

In view of the foregoing, early favorable consideration of this application is earnestly solicited.

Respectfully submitted,

By Elizabeth Hayes-Quebec
Elizabeth Hayes-Quebec

Date: May 19, 2004

Registration No.: 48,305

Tel.: 1-613-232-2486